CLAIMS

[Claim 1]

A pharmaceutical composition, comprising:

4-(2-fluoro-4-(3-(2-phenylacetyl)thioureido)phenoxy)-7-methoxy-N-methylquinoline-6-carboxamide or a pharmaceutically acceptable salt thereof; and

hydroxypropyl-β-cyclodextrin.

[Claim 2]

The pharmaceutical composition according to claim 1,

wherein the composition includes peaks at at least 5 or more diffraction angles 2θ (±0.2°) selected from 6.5, 7.8, 9.6, 12.4, 18.8, 21.2, 23.0, 24.5, and 26.0 (°) in powder X-ray structure diffraction.

[Claim 3]

The pharmaceutical composition according to claim 1 or 2,

wherein the composition includes peaks at chemical shift values [δ (ppm)] of 162.6, 130.4, 103.1, 82.7, 73.3, 41.9, and 19.9 in solid ^{13}C-NMR.

[Claim 4]

The pharmaceutical composition according to any one of claims 1 to 3,

wherein the composition includes peaks at at least 5 or more absorption bands selected from 1663, 1352, 1225, 1156, 1032, 720, and 553 (cm^{-1}) in an infrared absorption spectrum.

[Claim 5]

The pharmaceutical composition according to any one of claims 1 to 4,

wherein hydroxypropyl-β-cyclodextrin is contained at 0.1 to 5.5 parts by mass with respect to 1 part by mass of 4-(2-fluoro-4-(3-(2-phenylacetyl)thioureido)phenoxy)-7-methoxy-N-methylquinoline-6-carboxamide or a pharmaceutically acceptable salt thereof.

[Claim 6]

The pharmaceutical composition according to any one of claims 1 to 5,

wherein the amount of hydroxypropyl-β-cyclodextrin is from 60 to 95 mass%, preferably from 76 to 85 mass% with respect to the total pharmaceutical composition.

[Claim 7]

The pharmaceutical composition according to any one of claims 1 to 6, further comprising:

a cellulose derivative.

[Claim 8]

The pharmaceutical composition according to any one of claims 1 to 7,

wherein the pharmaceutical composition is for oral administration, and preferably is a tablet or a granule, more preferably a tablet having a maximum diameter of 5 mm or less.

[Claim 9]

The pharmaceutical composition according to any one of claims 1 to 8,

the pharmaceutical composition produced by physical mixing,

wherein the physical mixing is a production method that does not include a step in which 4-(2-fluoro-4-(3-(2-phenylacetyl)thioureido)phenoxy)-7-methoxy-N-methylquinoline-6-carboxamide or a pharmaceutically acceptable salt thereof is converted into a solution state when the pharmaceutical composition is produced.

[Claim 10]

The pharmaceutical composition according to claim 9,

wherein the physical mixing is mixing or granulation, the granulation preferably being a dry granulation method, or a wet granulation method, more preferably

a crushing granulation method, a fluidized bed granulation method, a rolling bed granulation method, an extrusion granulation method, or a high shear granulation method.

[Claim 11]

The pharmaceutical composition according to claim 9 or 10, further comprising:

a fluidizer.

[Claim 12]

The pharmaceutical composition according to claim 11,

wherein the amount of the fluidizer is from 0.1 to 2 mass%, preferably from 0.2 to 1 mass% with respect to the total pharmaceutical composition.

[Claim 13]

The pharmaceutical composition according to claim 11 or 12, wherein the fluidizer is a silicic acid derivative.

[Claim 14]

A method for producing a pharmaceutical composition, by performing physical mixing of 4-(2-fluoro-4-(3-(2-phenylacetyl)thioureido)phenoxy)-7-methoxy-N-methylquinoline-6-carboxamide or a pharmaceutically acceptable salt thereof and hydroxypropyl-β-cyclodextrin.

[Claim 15]

The production method according to claim 14,

wherein the physical mixing is a production method that does not include a step in which 4-(2-fluoro-4-(3-(2-phenylacetyl)thioureido)phenoxy)-7-methoxy-N-methylquinoline-6-carboxamide or a pharmaceutically acceptable salt thereof is converted into a solution state when the pharmaceutical composition is produced.

[Claim 16]

The production method according to claim 14 or 15,

wherein the physical mixing is mixing or granulation.

[Claim 17]

The production method according to any one of claims 14 to 16,

wherein the physical mixing is mixing, a dry granulation method, or a wet granulation method.

[Claim 18]

The production method according to any one of claims 14 to 17,

wherein the physical mixing is mixing, a crushing granulation method, a fluidized bed granulation method, a rolling bed granulation method, an extrusion granulation method, or a high shear granulation method.